



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 301-496-7005
FAX: 301-402-0527

October 25, 2004

Michael E. Moreland, MSW
Director
VA Pittsburgh Healthcare System
University Drive
Pittsburgh, Pennsylvania 15240

Dear Sir or Madam:

The Office for Human Research Protections (OHRP) has approved the Federalwide Assurance (FWA) submitted by your institution. The identification number assigned to your institution's FWA is FWA00001282. This number will be required on certain forms; e.g., for certification of IRB review to funding authorities. A copy of the approved FWA is enclosed. Please be sure that any party within your institution that may have an interest in this document also receives a copy.

Your institution's FWA is approved for a period of 3 years, and must be renewed prior to the expiration date to keep it active. Any change (update) in the information provided in your FWA should be submitted to OHRP when the change occurs. To renew or update the FWA, please submit the FWA form, marking it appropriately in the upper right-hand corner as either a renewal or an update. Renewals and updates may be faxed to OHRP at (301) 402-0527.

Human subjects research for which this FWA applies may not be initiated at your institution until the research is reviewed by one of the institutional review boards (IRB) designated on your FWA. Your institution is responsible for ensuring that all collaborators on federally-conducted or -supported human subjects research, that is not otherwise exempt, have an assurance of compliance approved by OHRP or another OHRP acceptable means of assuring compliance (e.g., Unaffiliated Investigator Agreement).

The Terms of Assurance set out your institution's responsibilities for protecting human subjects in research, as well as the procedures that will be used to ensure these protections. If at any time you have any question about your FWA, please contact OHRP. For your information, federal regulations, policies, and guidance on the conduct of human subjects research may be found on the OHRP website at <http://ohrp.osophs.dhhs.gov/>.

Sincerely,

Janice Ferrara Walden, CIP
Team Leader – Assurances/IRB Registrations
Division of Policy and Assurances

Enclosure

VA PGH HCS
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DIRECTOR'S OFFICE

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HL

☐ New Filing

☒ Update or Renewal for FWA Number: 00001282

**U.S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For Domestic (U.S.) Institutions**

1. Institution Filing Assurance

Legal Name: VA Pittsburgh Healthcare System

City: Pittsburgh

State: PA

Zip Code: 15240

DHHS Institution Profile File (IPF) code, if known:

Federal Entity Identification Number (EIN), if known:

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

☒ Please check here if there are no additional components or alternate names.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)

3. Statement of Principles

This Institution assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document(s). (*indicate below*)

☒ ***The Belmont Report***

☐ ***Other (please submit copy to OHRP with this Assurance)***

4. Applicability

(a) This Institution assures that all of its activities related to federally-conducted or -supported human subject research will comply with the **Terms of Assurance for Protection of Human Subjects for Institutions Within the United States**. NOTE: The Terms of Assurance are contained in a separate document on the OHRP website.

(b) *Optional*: This Institution elects to apply the following to all of its human subject research regardless of source of support:

☐ 45 CFR 46 and all of its subparts (A,B,C,D)

☒ **Common Rule** (e.g., 45 CFR 46, subpart A)

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance (*if the IRB is not previously registered with DHHS or has not provided a membership roster to DHHS, please attach the appropriate IRB registration materials available on the OHRP website*).

NOTE: Reliance on another institution's IRB or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions involved may develop their own agreement. Future designation of other IRBs requires update of the FWA.

DHHS IRB Registration Number	Name of IRB As Registered with DHHS
00000711 0000712	VA Pittsburgh Healthcare System IRB #1 (IORG 0000423) #2

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: **Steven**

Middle Initial: **H.**

Last Name: **Graham**

Degrees or Suffix (e.g., MD, PhD): **MD, PhD**

Institutional Title: **ACOS/R&D**

Institution: **VA Pittsburgh Healthcare System**

Telephone: **412-688-6104**

FAX: **412-688-6945**

E-Mail: **steven.graham@med.va.gov**

Address: **Research and Development (151-U), University Drive**

City: **Pittsburgh**

State: **PA**

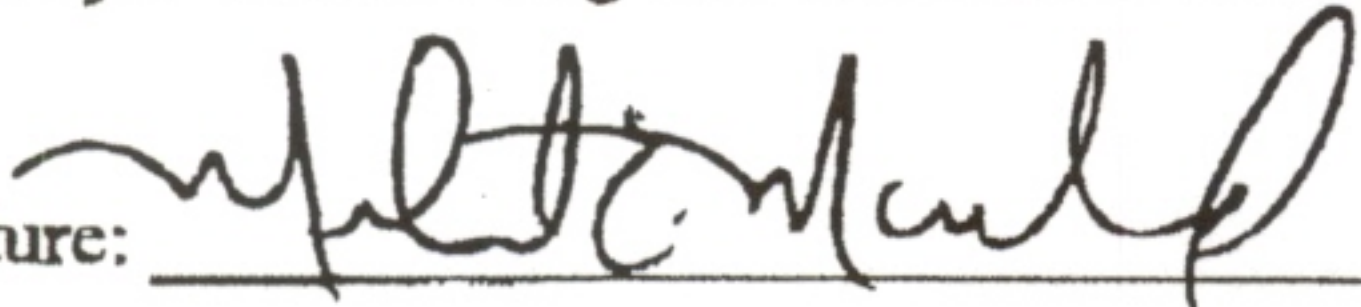
Zip Code: **15240**

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB Chairperson or IRB member)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing all research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide oversight for all research conducted under this Assurance. These IRB(s) will comply with the **Terms of Assurance** and possess appropriate knowledge of the local context in which this Institution's research will be conducted. I understand that all collaborating institutions engaged in federally-conducted or -supported human subject research must submit their own Assurance.

All information provided with this Assurance is up to date and accurate. *I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.*

Signature:  Date: 8/27/04

First Name: Michael Middle Initial: E. Last Name: Moreland

Degrees or Suffix (e.g., MD, PhD): MSW Institutional Title: Director

Telephone: 412-688-6100 FAX: 412-688-6789 E-Mail: michael.moreland@med.va.gov

Address: University Drive

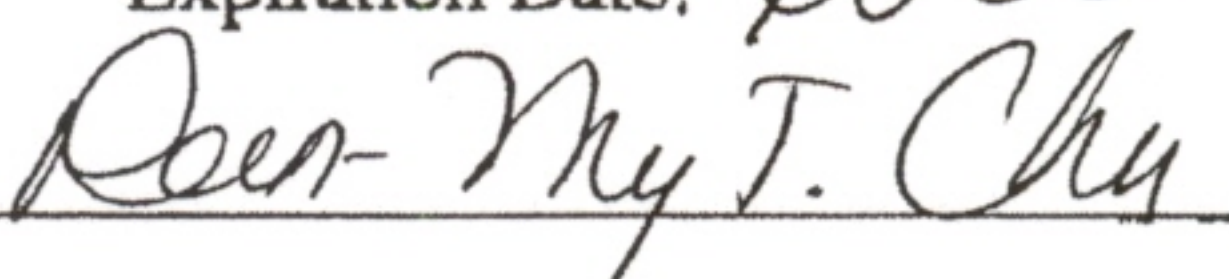
City: Pittsburgh State: PA Zip Code: 15240

NOTE: Facilities operated by the U.S. Government may require Department or Agency clearance. Please contact the relevant Department or Agency Human Protections Officer before forwarding this Assurance to OHRP.

8. DHHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to DHHS by the above Institution is hereby approved.

Assurance Number: FWA 00001282 Expiration Date: 08 Oct 2007

Signature of DHHS Approving Official:  Date: 08 Oct 2004

Dan-My T. Chu, Ph.D.
OPHS/OS/DHHS
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Phone: 301-402-2239
Fax: 301-402-0527

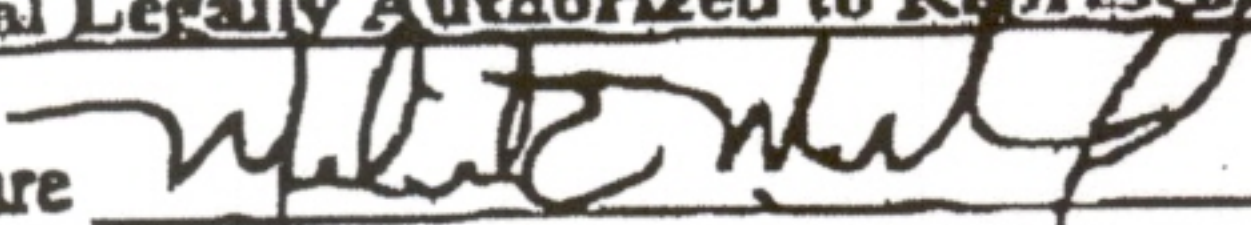
Department of Health and Human Services
Federalwide Assurance of Protection for Human Subjects

**ADDITIONAL PAGE REQUIRED FOR
DEPARTMENT OF VETERANS AFFAIRS
VETERANS HEALTH ADMINISTRATION FACILITIES**

VA Pittsburgh Healthcare System

assures that all of its pertinent activities related to human subject research will comply with all requirements of Department of Veterans Affairs regulations at Title 38 Code of Federal Regulations Part 16 (38 CFR 16), and all other pertinent Department of Veterans Affairs policies and procedures, including policies and procedures of the Office of Research Compliance and Assurance (ORCA) and the Office of Research & Development (ORD), issued in Manuals, Handbooks and other relevant authorized Directives.

(7a.) Official Legally Authorized to Represent the Institution (VA Medical Center Director):

Signature  Date: 8/26/04

First Name: Michael Middle Initial: E Last Name: Moreland

Degree or Suffix (e.g., MD, PhD) Institutional Title: Director

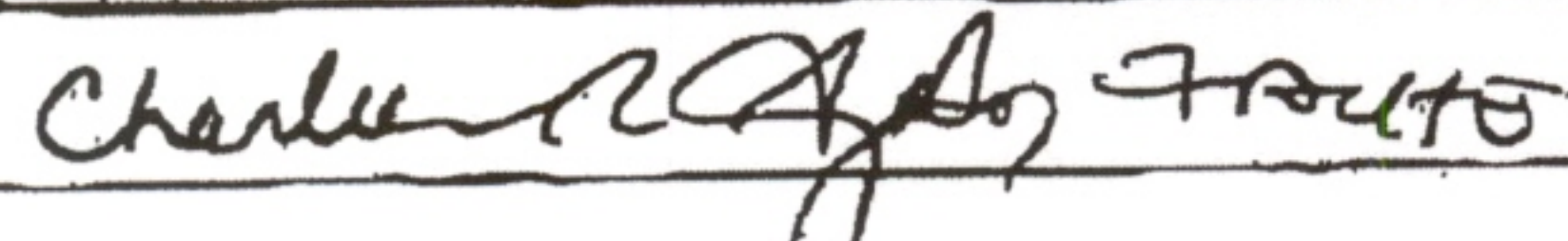
Human subject protection training last taken on: 8/30/2004

Address: University Drive

City: Pittsburgh State: PA Zip Code: 15240

Telephone: 412-688-6100 FAX: 412-688-6121 E-Mail: michael.moreland@med.va.gov

(7b.) Official Legally Authorized to Concur in the Institution's Approval (VHA VISN Director):

Signature  Date: 8/26/04

First Name: Charleen Middle Initial: R Last Name: Szabo

Degree or Suffix (e.g., MD, PhD) FACHE Institutional Title: Director, VISN # 4

Human subject protection training last taken on:

Address: University Drive

City: Pittsburgh State: PA Zip Code: 15240

Telephone: 412-784-3939 FAX: 412-784-3940 E-Mail: cheri.szabo@med.va.gov

(7c.) Department of Veterans Affairs Approval

Section below to be completed by the Office of Research Oversight

This Federal-wide Assurance of Protection for Human Subjects is hereby approved for submission to the Department of Health and Human Services (HHS).

VHA Recommending Official

Signature of VA Recommending Official:

Name: 
Priscilla A. Craig

Date: 9/29/04

Title: Health Science Specialist, Federal Wide Assurances
Office of Research Oversight

Signature of VA Approving Official:

Name: 
David A. Weber, Ph.D.

Date: 9/30/04

Title: Chief Officer
Office of Research Oversight (ORO)

Any Additional Comments:

Office of Research Oversight (10R)
811 Vermont Avenue, NW, Suite 574
Washington, DC 20420

Phone: (202) 565-8162
FAX: (202) 565-9194

E-mail: Priscilla.craig@hq.med.va.gov